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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

In re Selenious Acid Litigation

No. 2:24-cv-07791-BRM-CLW (Consolidated)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3 of the United States District Court for the District of New Jersey and the Stipulation and Amended Scheduling Order (ECF No. 124), Plaintiff American Regent, Inc. (“ARI”) and Defendants Aspiro Pharma Ltd. (“Aspiro”), Cipla USA, Inc. and Cipla Limited (“Cipla”), Hikma Pharmaceuticals USA Inc. (“Hikma”), RK Pharma, Inc. (“RK Pharma”), Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries Inc. (“Sun”), and Zydus Pharmaceuticals (USA), Inc. (“Zydus”) (collectively, “Defendants”), hereby

submit their Joint Claim Construction and Prehearing Statement for U.S. Patent Nos. 11,998,565 (the “’565 patent”) and 12,150,957 (“the ’957 Patent”) (collectively, the “Asserted Patents”).

I. BACKGROUND

Pursuant to L. Pat. R. 4.1(a), on March 20, 2025, the parties exchanged proposed claim terms for construction. ARI proposed that no terms required construction, whereas Defendants proposed three terms for construction. Pursuant to L. Pat. R. 4.2(a)–(b), on March 24, 2025, ARI exchanged preliminary claim constructions for all the terms identified in Defendants’ March 20, 2025 disclosure and identified intrinsic as well as extrinsic evidence in support of ARI’s proposed preliminary constructions. Defendants proposed that all the identified terms are indefinite under 35 U.S.C. § 112. Pursuant to L. Pat. R. 4.2(b) on March 24, 2025, ARI identified intrinsic as well as extrinsic evidence to support its proposed preliminary constructions. Pursuant to L. Pat. R. 4.2(c), on March 31, 2025, the parties exchanged intrinsic and extrinsic evidence opposing the other side’s positions concerning the identified claim terms from the Asserted Patents.

The parties have agreed that any issues of indefiniteness should be addressed by the Court after the parties have completed fact and expert discovery. Because the only issue with terms relates to Defendants’ position of indefiniteness, the parties agree that there is no need for a claim construction hearing.

II. CONSTRUCTION OF PATENT TERMS

A. Agreed Upon Claim Constructions

Pursuant to L. Pat. R. 4.3(a), the parties have not agreed to the construction of the three claim terms proposed by Defendants as needing construction.

B. Disputed Claim Terms

Pursuant to L. Pat. R. 4.3(b), attached hereto as Exhibit A is a chart identifying the claim

terms and phrases from the Asserted Patents in dispute and the parties' proposed constructions, as well as intrinsic and extrinsic evidence that each party intends to rely upon either to support its proposed constructions or to oppose the other party's proposed constructions. As a result of the parties' agreement to delay resolution of indefiniteness issues, there are currently three claim terms at issue. Regardless, the parties provide their identified intrinsic and extrinsic evidence regarding all three terms out of an abundance of caution.

C. Claim Terms Whose Construction Will Be Most Significant

Pursuant to L. Pat. R. 4.3(c), the parties believe that construction of the terms listed in Exhibit A are equally significant to the resolution of the case. The parties do not believe that construction of any of the terms listed in Exhibit A will be dispositive or substantially conducive to promoting settlement.

D. Anticipated Length of Time Necessary for the Claim Construction Hearing

Pursuant to L. Pat. R. 4.3(d), to conserve the resources of the parties and the Court, the parties do not anticipate that a hearing is needed because the only issue is indefiniteness, which the parties agreed should be addressed by the Court after the parties have completed fact and expert discovery.

E. Identification of Witnesses for the Claim Construction Hearing

1. ARI's Witnesses

None.

2. Defendants' Witnesses

None.

Dated: April 4, 2025

/s/ Charles H. Chevalier

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Term (Patent, Claim)	ARI's Proposed Construction	ARI's Exemplary Evidence	Defendants' Proposed Construction	Defendants Exemplary Evidence
<p>fluoride in an amount of 0.0001 µg to 2.7 µg</p> <p>/</p> <p>0.0001 µg to 2.7 µg of fluoride</p> <p>/</p> <p>fluoride in an amount of 0.0001 µg to 2.7 µg per 1 mL of the injectable composition ('565 patent, Claims 1–14, 16, 18, 22–29) ('957 patent, Claims 1, 3, 4, 6–12, 14–18, 26, 27, 29, 30)</p>	<p><i>Plain and ordinary meaning:</i></p> <p>an amount of fluoride from 0.0001 µg to 2.7 µg, inclusive / an amount of fluoride from 0.0001 µg to 2.7 µg, inclusive / a concentration of fluoride in the injectable composition from 0.0001 µg/mL to 2.7 µg/mL, inclusive</p>	<p>ARI reserves the right to rely on any evidence cited by Defendants in support of their proposed construction of this term, or cited by Defendants in opposition to ARI's proposed construction of this term.</p> <p>Pursuant to L. Pat. R. 4.3(e), and subject to the Court's preferences regarding live witness testimony, ARI intends to offer expert testimony from Dr. George Phillip Ayers, Pharm.D. through declaration and/or deposition. Dr. Ayers will provide testimony and evidence (1) regarding the state of the art and ARI's inventions; (2) in support of ARI's claim construction positions, including the intrinsic</p>	<p>Indefinite.</p>	<p><u>'565 patent, including, but not limited to:</u></p> <ul style="list-style-type: none"> • 17:3-20 • 66:34 – 67:22 • Tables 2, 3, and 4 • Example 9 • Claims 1-14, 16, 18, 22-29 <p><u>Prosecution file history of the '565 patent</u></p> <p><u>'957 patent, including, but not limited to:</u></p> <ul style="list-style-type: none"> • 17:8-25 • Tables 2, 3, and 4 • Example 9 • Claims 1-18, 26, 27, 29, 30 <p><u>Prosecution file history of the '957 patent</u></p> <p>Defendants may also rely on the references cited in the patents-in-suit, as well as prior art</p>

		<p>and extrinsic evidence cited in the chart above; (3) in rebuttal to Defendants' claim construction positions; and/or (4) regarding the meaning of the terms identified above to a person of ordinary skill in the art. ARI reserves the right to rely on any witness at trial that may be disclosed hereafter pursuant to the Court's Amended Scheduling Order (ECF No. 124). ARI further reserves the right to rely on any expert opinions or declarations provided in expert discovery. ARI objects to the Defendants' relying on expert testimony or declarations to the extent Defendants fail to adequately disclose the identity of expert witnesses.</p> <p>Intrinsic Evidence: '565 Patent at 17:3-10, Table 35 at 67:1-22,</p>		<p>discussed during prosecution of the patents-in-suit.</p> <p>Defendants may also rely on any evidence identified by Plaintiff.</p> <p><u>Contentions:</u> Defendants' Invalidity Contentions, dated February 18, 2025, including any references cited therein.</p> <p>Defendants' Non-Infringement Contentions, dated February 18, 2025, including any references cited therein.</p> <p>Plaintiffs' Disclosure of Infringement Contentions to each Defendant, dated March 18, 2025, including any references cited therein.</p>
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		<p>Claims 1, 23 26, 27; '565 Patent Prosecution History, Original Claims (03/21/2023) at 82-91, Response to Office Action (12/13/2023) at 7-24, Response to Office Action (03/01/2024) at 7-11, Notice of Allowance (03/22/2024) at 1-10, Notice of Allowance (04/24/2024) at 1-6; '957 Patent at 17:8-15, Table 35 at 68:17-62, Claims 1, 26, 27, 29, 30; '957 Patent Prosecution History, Original Claims (05/23/24) at 1-9, Preliminary Amendment (05/23/24) at 7-10, Notice of Allowance (09/05/24) at 1-8, Notice of Allowance (10/09/24) at 1-5.</p> <p>Rebuttal evidence to be identified pursuant to L.Pat. R. 4.2(c).</p>		<p>Plaintiff's Response to Defendants' Invalidity Contentions, dated March 18, 2025, including any references cited therein.</p> <p><u>Extrinsic Evidence:</u> Defendants may introduce testimony from one or more experts supporting the meaning of this claim term. Pursuant to L. Pat. R. 4.5, Defendants may provide any expert certifications and/or declarations with its opening and/or responding Markman briefs. The expert(s) may offer opinions as to the technology, state of the art, and the meaning of this claim term as it would have been understood by a person of ordinary skill in the art at the time the asserted patents were filed, consistent with</p>
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				Defendants' proposal, the intrinsic record, and other extrinsic evidence known to the expert and other experts in the relevant field such as scientific publications, treatises, and/or dictionaries. The expert(s) may also provide opinions to rebut the opinions of Plaintiff's expert(s).
0.0001 µg to 0.2 µg of iodine / iodine in an amount of 0.0001 µg to 0.2 µg per 1 mL of the injectable composition ('565 patent, Claims 15-17, 19-21, 23, 29) ('957 patent, Claims 17, 19, 21-30)	<i>Plain and ordinary meaning:</i> an amount of iodine from 0.0001 µg to 0.2 µg, inclusive / a concentration of iodine in the injectable composition from 0.0001 µg/mL to 0.2 µg/mL, inclusive	ARI reserves the right to rely on any evidence cited by Defendants in support of their proposed construction of this term, or cited by Defendants in opposition to ARI's proposed construction of this term. Pursuant to L. Pat. R. 4.3(e), and subject to the Court's preferences regarding live witness testimony, ARI intends to offer expert testimony from Dr. George Phillip Ayers,	Indefinite.	<u>'565 patent, including, but not limited to:</u> <ul style="list-style-type: none"> • 1:28-32 • 17:3-20 • Tables 2, 3, and 4 • Claims 15-17, 19-21, 23, 29 <u>Prosecution file history of the '565 patent</u> <u>'957 patent, including, but not limited to:</u> <ul style="list-style-type: none"> • 1:25-34 • 17:8-25 • Tables 2, 3, and 4

		<p>Pharm.D. through declaration and/or deposition. Dr. Ayers will provide testimony and evidence (1) regarding the state of the art and ARI's inventions; (2) in support of ARI's claim construction positions, including the intrinsic and extrinsic evidence cited in the chart above; (3) in rebuttal to Defendants' claim construction positions; and/or (4) regarding the meaning of the terms identified above to a person of ordinary skill in the art. ARI reserves the right to rely on any witness at trial that may be disclosed hereafter pursuant to the Court's Amended Scheduling Order (ECF No. 124). ARI further reserves the right to rely on any expert opinions or declarations provided in expert discovery. ARI objects to the</p>	<ul style="list-style-type: none"> • Claims 17, 19-30 <p><u>Prosecution file history of the '957 patent</u></p> <p>Defendants may also rely on the references cited in the patents-in-suit, as well as prior art discussed during prosecution of the patents-in-suit.</p> <p>Defendants may also rely on any evidence identified by Plaintiff.</p> <p><u>Contentions:</u> Defendants' Invalidity Contentions, dated February 18, 2025, including any references cited therein.</p> <p>Defendants' Non-Infringement Contentions, dated February 18, 2025, including any references cited therein.</p>
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		<p>Defendants' relying on expert testimony or declarations to the extent Defendants fail to adequately disclose the identity of expert witnesses.</p> <p>Intrinsic Evidence: '565 Patent at 17:3-10, Table 35 at 67:1-22, Claims 7, 15, 16, 26, 27, '565 Patent Prosecution History, Original Claims (03/21/2023) at 82-91, Response to Office Action (12/13/2023) at 7-24, Response to Office Action (03/01/2024) at 7-11; '957 Patent at 17:8-15, Table 35 at 68:17-62, Claims 16, 17, 19, 20, 29; '957 Patent Prosecution History, Original Claims (05/23/24) at 1-9, Preliminary Amendment (05/23/24) at 7-10, Notice of Allowance (09/05/24) at 1-8, Notice of</p>		<p>Plaintiffs' Disclosure of Infringement Contentions to each Defendant, dated March 18, 2025, including any references cited therein.</p> <p>Plaintiff's Response to Defendants' Invalidity Contentions, dated March 18, 2025, including any references cited therein.</p> <p><u>Extrinsic Evidence:</u> Defendants may introduce testimony from one or more experts supporting the meaning of this claim term. Pursuant to L. Pat. R. 4.5, Defendants may provide any expert certifications and/or declarations with its opening and/or responding Markman briefs. The expert(s)</p>
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		<p>Allowance (10/09/24) at 1-5.</p> <p>Rebuttal evidence to be identified pursuant to L. Pat. R. 4.2(c).</p>		<p>may offer opinions as to the technology, state of the art, and the meaning of this claim term as it would have been understood by a person of ordinary skill in the art at the time the asserted patents were filed, consistent with Defendants' proposal, the intrinsic record, and other extrinsic evidence known to the expert and other experts in the relevant field such as scientific publications, treatises, and/or dictionaries. The expert(s) may also provide opinions to rebut the opinions of Plaintiff's expert(s).</p>
<p>Water ('565 patent, All Claims) ('957 patent, Claims 1, 3, 4, 6–12, 14–19, 21–30)</p>	<p><i>Plain and ordinary meaning:</i></p>	<p>ARI reserves the right to rely on any evidence cited by Defendants in support of their proposed construction of this term, or cited by Defendants in opposition to ARI's proposed construction</p>	<p>Indefinite.</p>	<p><u>'565 patent, including, but not limited to:</u></p> <ul style="list-style-type: none"> • 1:11-2:43 • 2:47-5:26 • 5:32-42:53 • Examples 1-12 • Claims 1-29

		<p>of this term.</p> <p>Pursuant to L. Pat. R. 4.3(e), and subject to the Court's preferences regarding live witness testimony, ARI intends to offer expert testimony from Dr. George Phillip Ayers, Pharm.D. through declaration and/or deposition. Dr. Ayers will provide testimony and evidence (1) regarding the state of the art and ARI's inventions; (2) in support of ARI's claim construction positions, including the intrinsic and extrinsic evidence cited in the chart above; (3) in rebuttal to Defendants' claim construction positions; and/or (4) regarding the meaning of the terms identified above to a person of ordinary skill in the art. ARI reserves the right to rely on any witness at trial that may</p>	<p><u>Prosecution file history of the '565 patent</u></p> <p><u>'957 patent, including, but not limited to:</u></p> <ul style="list-style-type: none"> • 1:11-2:43 • 2:47-5:26 • 5:30-42:39 • Examples 1-12 • Claims 1, 3-4, 6-10, 12, 14-19, 21-30 <p><u>Prosecution file history of the '957 patent</u></p> <p>Defendants may also rely on the references cited in the patents-in-suit, as well as prior art discussed during prosecution of the patents-in-suit.</p> <p>Defendants may also rely on any evidence identified by Plaintiff.</p> <p><u>Contentions:</u> Defendants' Invalidity Contentions, dated February 18, 2025, including any</p>
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		<p>be disclosed hereafter pursuant to the Court's Amended Scheduling Order (ECF No. 124). ARI further reserves the right to rely on any expert opinions or declarations provided in expert discovery. ARI objects to the Defendants' relying on expert testimony or declarations to the extent Defendants fail to adequately disclose the identity of expert witnesses.</p> <p>Intrinsic Evidence: '548 Patent at Abstract, 1:23, 2:64, 3:2, 3:12, 3:17, 3:23, 3:30, 3:39, 3:44, 3:55, 3:61, 3:67, 4:13, 4:18, 4:57, 7:34, 7:53, 9:33, 9:43, 9:63, 10:2, 10:6, 10:12, 10:16, 10:30, 10:36, 18:11, 18:18, 21:38, 21:59, 22:54, 22:65, 27:56, 28:25, 28:27, 36:2, 36:6, 37:10, 39:42, 40:27, 41:3, 41:8, 41:48, 42:12,</p>		<p>references cited therein.</p> <p>Defendants' Non-Infringement Contentions, dated February 18, 2025, including any references cited therein.</p> <p>Plaintiffs' Disclosure of Infringement Contentions to each Defendant, dated March 18, 2025, including any references cited therein.</p> <p>Plaintiff's Response to Defendants' Invalidity Contentions, dated March 18, 2025, including any references cited therein.</p> <p><u>Extrinsic Evidence:</u></p> <p>The parties' Preliminary Injunction briefing, including but</p>
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		<p>Claims 1, 15, 23, 24, 26, 27, 29, 31, 34; '022 Patent at Abstract, 1:23, 2:64, 3:2, 3:12, 3:23, 3:30, 3:39, 3:44, 3:55, 3:61, 3:67, 4:13, 4:18, 4:57, 7:36, 7:55, 9:36, 9:46, 9:66, 10:5, 10:9, 10:15, 10:19, 10:33, 10:39, 10:46, 18:15, 18:22, 21:42, 28:6, 28:8, 36:2, 36:6, 37:9, 39:41, 40:26, 41:2, 41:7, 41:47, 42:11, Claims 1, 12, 18; '565 Patent at Abstract, 1:23, 2:64, 3:2, 3:12, 3:17, 3:23, 3:30, 3:39, 3:44, 3:55, 3:61, 3:67, 4:13, 4:18, 4:56, 7:36, 7:55, 9:36, 9:46, 9:66, 10:33, 10:39, 18:27, 18:34, 21:54, 28:29, 28:31, 36:8, 36:12, 37:15, 39:49, 40:34, 41:10, 41:15, 41:55, 42:20, 58:37, 59:17, 71:36, 72:9, 72:62, 73:2, Claims 1, 15, 26, 27; '956 Patent at Abstract, 1:23, 2:64, 3:2, 3:12, 3:17, 3:23, 3:30, 3:39, 3:44, 3:55, 3:61, 3:67,</p>	<p>not limited to the declarations and exhibits thereto. Defendants may introduce testimony from one or more experts supporting the meaning of this claim term. Pursuant to L. Pat. R. 4.5, Defendants may provide any expert certifications and/or declarations with its opening and/or responding Markman briefs. The expert(s) may offer opinions as to the technology, state of the art, and the meaning of this claim term as it would have been understood by a person of ordinary skill in the art at the time the asserted patents were filed, consistent with Defendants' proposal, the intrinsic record, and other extrinsic evidence known to the expert and other experts in the relevant field such as</p>
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